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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,959	08/26/2003	Choong-Chin Liew	4231/2032	7379

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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,959	LIEW ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to an isolated biomarker comprising at least one polynucleotide, classified in class 536, subclass 23.1.

This group is composed of multiple distinct inventions, each of which is drawn to a specific combination of nucleic acid molecules recited in Tables 2 and 3. The nucleic acids of tables 2 and 3 are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. Each nucleic acid sequence is drawn to a patentably distinct nucleic acid. Further, each combination of nucleic acid sequences is distinct from each other and does not render the other obvious. For example, a search of the combination of nucleic acid molecules A and B requires a separate search than the combination of nucleic acid molecules C and D. Moreover, the combination A and B will not anticipate or render obvious combination C and D. Thus, this group is composed of multiple distinct inventions, which are combination of nucleic acid molecules recited in Tables 2 and 3.

If Group I is elected, Applicant must elect a single invention that is one combination of nucleic acid molecules set forth in Tables 2 and 3. Claims that do not read on the elected combination will be withdrawn from consideration.

However, if the elected combination of nucleic acid sequences is found to be allowable, claims containing patentably indistinct combinations comprising the allowable combination of sequences will be rejoined and fully examined under all required statues.

II. Claims 6-10, drawn to an isolated biomarker comprising at least one polypeptide, classified in class 530, subclasses 300 and 350.

This group is composed of multiple distinct inventions, each of which is drawn to a specific combination of polypeptide molecules recited in Tables 2 and 3. The polypeptides of tables 2 and 3 are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. Further, each combination of polypeptides is distinct from each other and does not render the other obvious. For example, a search of the combination of polypeptides A and B requires a separate search than the combination of polypeptides C and D. Moreover, the combination A and B will not anticipate or render obvious combination C and D. Thus, this group is composed of multiple distinct inventions, which are combination of polypeptides recited in Tables 2 and 3.

If Group II is elected, Applicant must elect a single invention that is one combination of polypeptides set forth in Tables 2 and 3. Claims that do not read on the elected combination will be withdrawn from consideration. However, if the elected combination of polypeptides is found to be allowable, claims containing patentably indistinct combinations comprising the allowable

combination of sequences will be rejoined and fully examined under all required statues.

III. Claim 11, drawn to a method of identifying an inhibitor of B2M activity, comprising comparing the proliferation of chondrocytes, classified in class 435, subclass 29.

IV. Claims 12-15, drawn to a method of identifying an inhibitor of B2M activity comprising comparing the level of differential expression of a biomarker comprising at least one polynucleotide sequence, classified in class 435, subclass 6.

This group is composed of multiple distinct inventions, each of which is drawn to a method of using a specific combination of nucleic acid molecules recited in Tables 2 and 3. The nucleic acids of tables 2 and 3 are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. Each nucleic acid sequence is drawn to a patentably distinct nucleic acid. Further, each combination of nucleic acid sequences is distinct from each other and does not render the other obvious. For example, a search of the combination of nucleic acid molecules A and B requires a separate search than the combination of nucleic acid molecules C and D. Moreover, the combination A and B will not anticipate or render obvious combination C and D. Thus, this group is composed of multiple distinct inventions, which are combination of nucleic acid molecules recited in Tables 2 and 3.

If Group IV is elected, Applicant must elect a single invention that is a method of using one combination of nucleic acid molecules set forth in Tables 2 and 3. Claims that do not read on the elected combination will be withdrawn from consideration. However, if the elected combination is found to be allowable, claims containing patentably indistinct combinations comprising the allowable combination will be rejoined and fully examined under all required statues.

V. Claims 16-19, drawn to a method of identifying an inhibitor of B2M activity comprising comparing the level of differential expression of a biomarker comprising a polypeptide, classified in class 435, subclass 7.1.

This group is composed of multiple distinct inventions, each of which is drawn to a method of using a specific combination of polypeptide molecules recited in Tables 2 and 3. The polypeptides of tables 2 and 3 are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. Further, each combination of polypeptides is distinct from each other and does not render the other obvious. For example, a search of the combination of polypeptides A and B requires a separate search than the combination of polypeptides C and D. Moreover, the combination A and B will not anticipate or render obvious combination C and D. Thus, this group is composed of multiple distinct inventions, which are methods of using a combination of polypeptides recited in Tables 2 and 3.

If Group V is elected, Applicant must elect a single invention that is a method of using one combination of polypeptides set forth in Tables 2 and 3. Claims that do

not read on the elected combination will be withdrawn from consideration. However, if the elected combination is found to be allowable, claims containing patentably indistinct combinations comprising the allowable combination will be rejoined and fully examined under all required statues.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product of Group I can be used in a materially different process such as the manufacture of proteins encoded by the nucleic acid molecules.

Inventions of Group II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptides of Group II can be used in a materially different process such as the identification of binding partners for the proteins or for *in vitro* assays of protein activity.

The nucleic acids of Group I, and the polypeptides of Group II are chemically, biologically, and functionally distinct from each other and thus one does not render the other

obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

The inventions of Groups III-V are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups III-V comprise steps which are not required for or present in the methods of the other groups: comparing the proliferation of chondrocytes (Group III), comparing the level of polynucleotide expression (Group IV), and comparing the level of polypeptide expression (Group V). The end results of the methods are different: the methods identify inhibitors of B2M activity based upon proliferation rate (Group III), polynucleotide expression (Group IV), and polypeptide expression (Group V) and thus will identify different sets of compounds as inhibitors. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the inventions of Groups I-II and Groups III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I-II are not necessarily used in or made by the methods of Groups III-V.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for

examination purposes as indicated is proper. With regard to the restriction between each of the polynucleotide sequence and between each of the polypeptide sequences, the inventions are independent or distinct for the reasons given above and require a different field of search (see MPEP § 808.02), and thus restriction for examination purposes as indicated is proper. Each one or combination of polynucleotides and each one or combination of polypeptides, requires a separate search of the patent and non-patent literature to identify the specific combination. The searches for each combination are not coextensive, and the additional searching required to search more than one combination would impose a serious search burden.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with the 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy,

Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER